The odour acceptability of oral flucloxacillin formulations assessed using a human sensory panel

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INTRODUCTION

- ➤ Palatability 'the overall appreciation of a medicinal product in relation to its smell, taste, aftertaste and texture', as highlighted by the EMA Guideline on the Development of Age-appropriate Formulations is one of the key elements of paediatric medicine acceptability.
- The relationship between medicine taste and acceptability has received much attention, however, the role that the odour of medicine plays in patient acceptability has been somewhat neglected to date.
- ➤ Smell not only influences a patient's perception of a medicine's acceptability prior to ingestion, it is also the main contributing sense to the determination of a substance's flavour (Spence, 2015).
- ➤ Oral antibiotic acceptability is a key consideration to ensure adherence and effective treatment. Flucloxacillin, a widely prescribed oral antibiotic, is reported as an unpalatable antibiotic for paediatric patients, with its malodour a contributing factor (Elgammal et al., 2023)

Objectives

The overall aim of our research programme is to explore the role of smell in drug product palatability. This preliminary study is focused on the use of oral antibiotics in a paediatric primary care setting. The aim of this study is to compare the odour of a range of commercial and novel flucloxacillin formulations for paediatric patients.

METHODS



40 volunteers attended to the School of Pharmacy for 2-3 hours



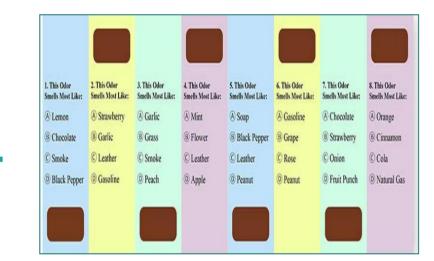
The study information sheet was provided, and questions were answered



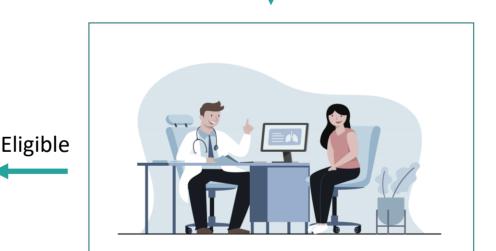
Volunteers were asked to sign an informed consent form



Volunteers were trained to carry out the smell test and were familiarized with the smell questionnaire



Volunteers' smell acuity was assessed using 8-item Sensonics™ smell test



Volunteers met a registered medical doctor one by one for health screening



Volunteers were asked to smell 5 flucloxacillin samples and to complete the smell questionnaire

An aqueous solution (5 ml) containing 250 mg flucloxacillin sodium

A commercial solution (5 ml) containing 250 mg flucloxacillin sodium

A commercial capsule containing 250 mg flucloxacillin sodium.

A minitablet formulation containing 250 mg flucloxacillin sodium

• Minitablet formulation containing 250 mg flucloxacillin sodium with silica as an odour suppressant

Figure 1. Odour assessment methodology steps

CONCLUSION

- ➤ Participants were not able to detect the smell of flucloxacillin formulated as capsule and minitablets with silica.
- Flucloxacillin minitablets can be an alternative age-appropriate formulation for children which can play a role in improving palatability and adherence to antibiotic treatment.
- ➤ Next steps are to further investigate flucloxacillin minitablets and capsule formulations for paediatric patients, by evaluating and optimising their overall palatability and swallowability.

RESULTS

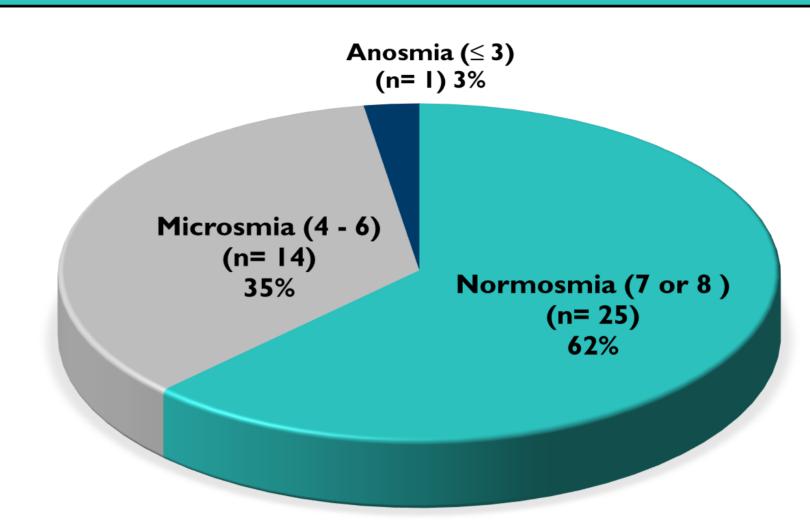


Figure 2. Volunteers smell test scores using 8-item Sensonics™ test (n=40)

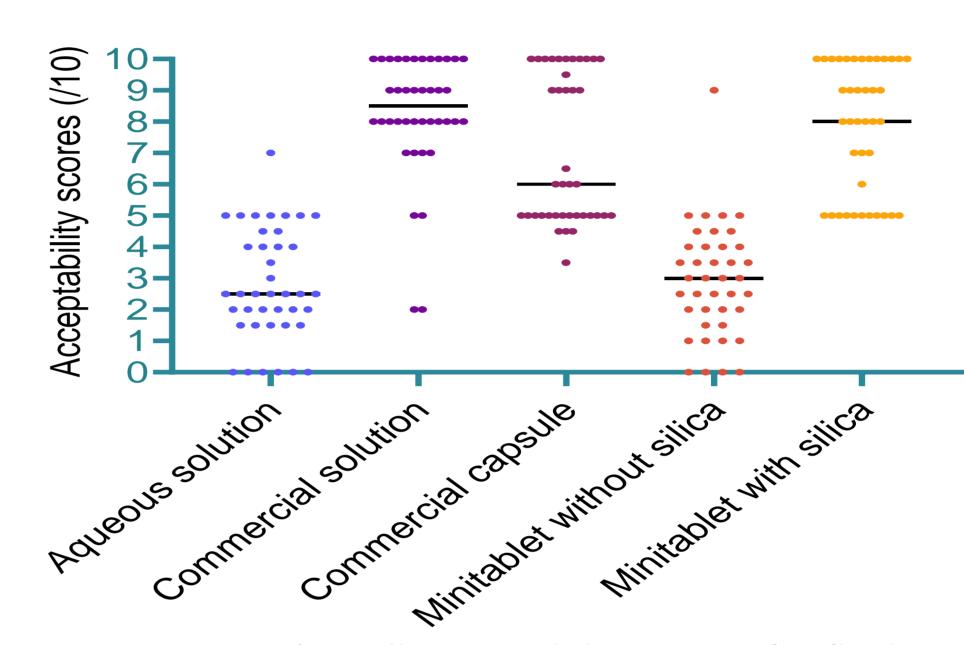


Figure 4. Participants' smell acceptability scores for flucloxacillin samples *The solid black line indicates the mean acceptability score for each sample

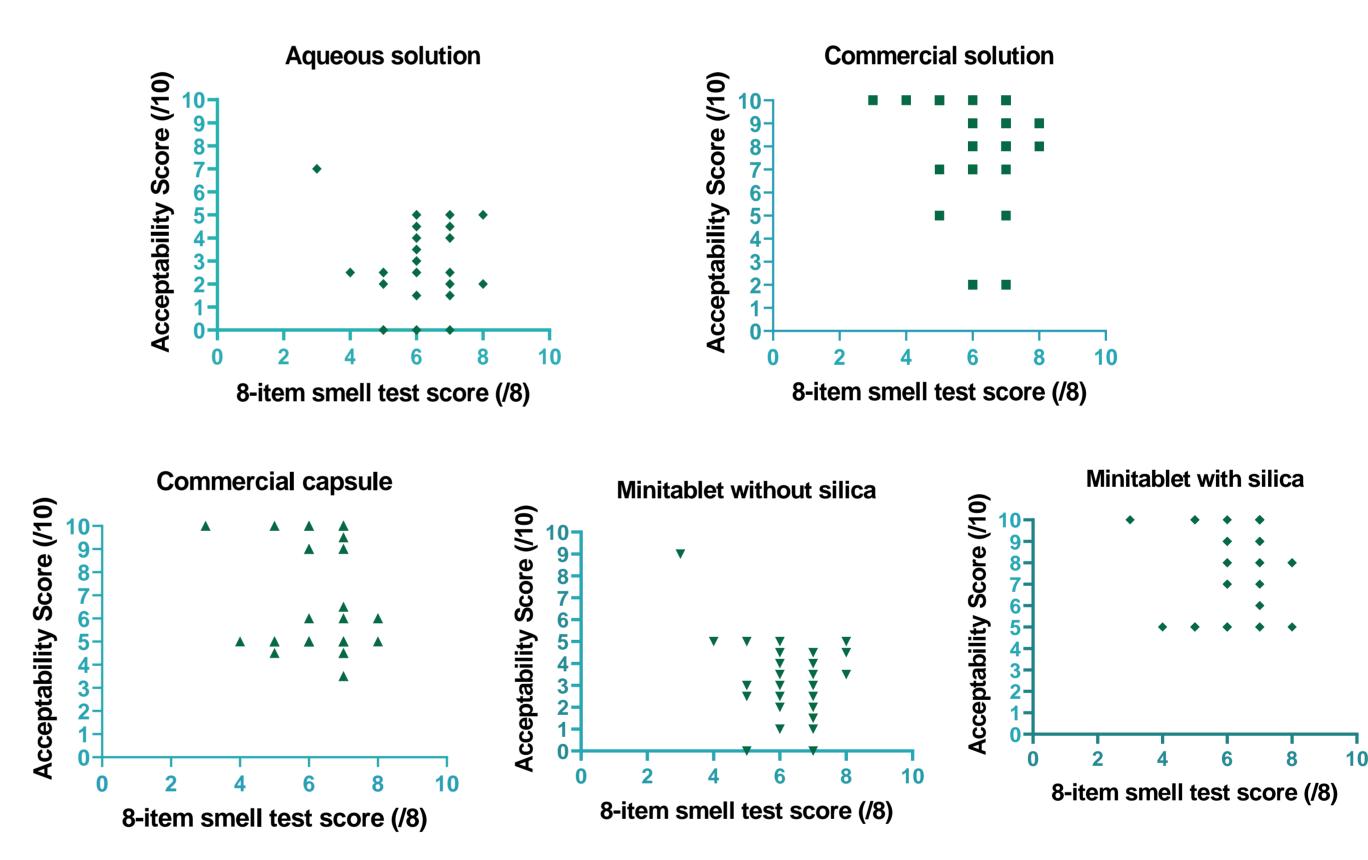


Figure 3. Individual smell acceptability scores of flucloxacillin samples based on participants' 8-item Sensonics™ smell test scores

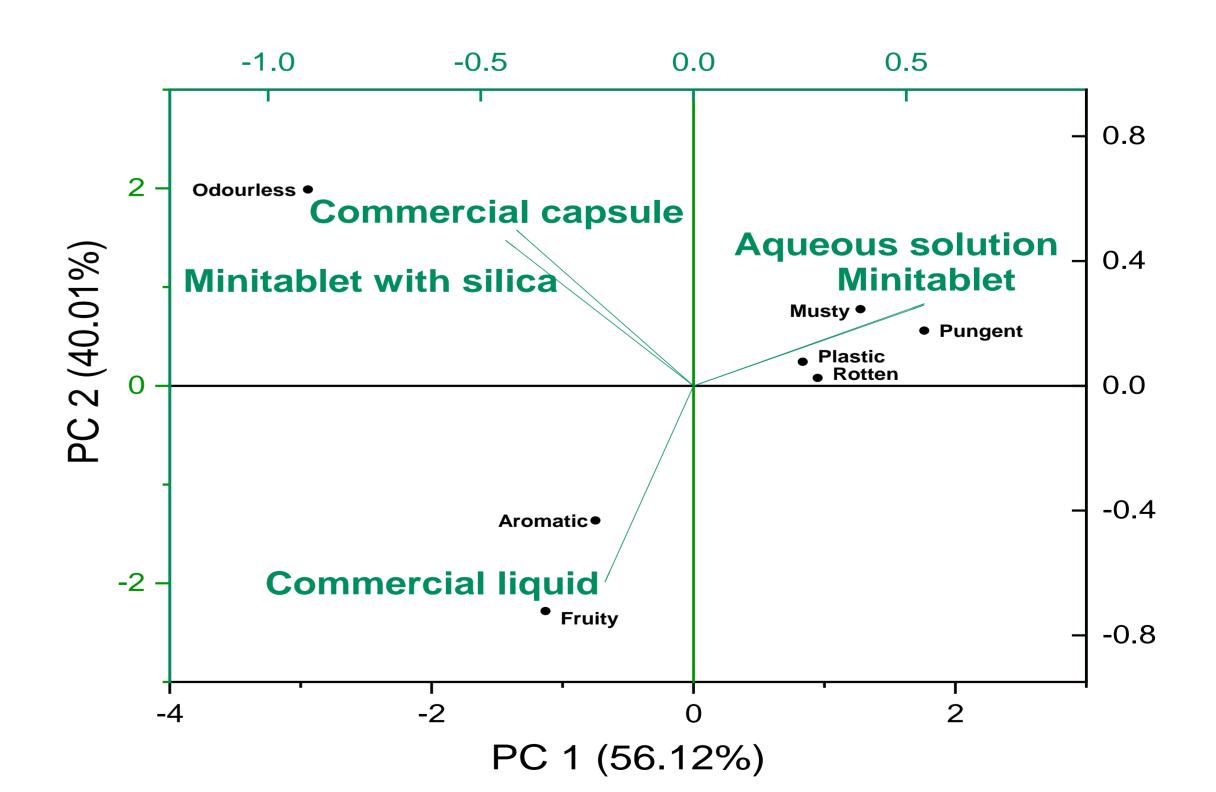


Figure 5. Principal component analysis (PCA) biplot of smell sensory attributes for flucloxacillin samples evaluated by human panel (n=40)

References

Spence, C. (2015). Just how much of what we taste derives from the sense of smell? Flavour, 4(1), 1–10. Elgammal, A., Ryan, J., Bradley, C., Crean, A., Bermingham, M.: The impact of drug palatability on prescribing and dispensing of antibiotic formulations for paediatric patients: a cross-sectional survey of general practitioners and pharmacists. Fam. Pract. 1–8 (2023). https://doi.org/10.1093/fampra/cmad071